DEC 12 2013

K132523
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TOSHIBA AMERICA MEDICAL SYSTEMS, INC.
2441 Michelle Drive, Tustin, CA 92780
Phone: (714) 730-5000

510(k) – SUMMARY

1. **SUBMITTER'S NAME:**
   Toshiba America Medical Systems, Inc.

2. **ADDRESS:**
   2441 Michelle Drive
   Tustin, CA. 92780-2068

3. **ESTABLISHMENT REGISTRATION:**
   2020563

4. **CONTACT PERSON:**
   Paul Biggins
   Director, Regulatory Affairs
   (714) 730-5000

5. **DATE PREPARED:**
   August 9, 2013

6. **TRADE NAME(S):**
   MyoPerfusion, CSMP-001A

7. **COMMON NAME:**
   System, X-ray, Computed Tomography

8. **DEVICE CLASSIFICATION:**
   Class II (per 21 CFR 892.1750)

9. **PRODUCT CODE / DESCRIPTION:**
   90JAK – System, Computed Tomography

10. **PERFORMANCE STANDARD:**
    None

11. PREDICATE DEVICES:

Device Name	Vitrea® CT Myocardial Analysis	CardIQ Xpress 2.0	syngo.CT Cardiac Function
Marketed By	Vital Images, Inc.	GE Medical Systems	Siemens Medical Solutions, Inc.
510(k) Clearance Number	K112531	K073138	K110366
Clearance Date	November 18, 2011	February 26, 2008	April 12, 2011

12. REASON FOR SUBMISSION:

New accessory software

13. DEVICE DESCRIPTION:

This device processes ECG-gated contrast enhanced cardiac scan data using MPR generated images according to the cardiac axis. The software generates polar maps, perfusion index (PI) map and Transmural Perfusion Ration (TPR) maps based upon the measured CT values of the tissue within the specified region of interest. The software displays the values associated with the generation of the Perfusion Index and TPR Maps. PI is the ratio of the Mean Myocardial CT value to the LV blood pool CT value. TPR is provided as a ratio per sector of the Endocardial CT value to the mean Epicardial CT value.

14. INDICATIONS FOR USE:

This software is intended to be used for the visualization of non-reversible perfusion defects (hypo/hyper dense areas) in patients with angina or with a previous myocardial infarct. Included software tools may aid a trained user in monitoring the disease state and treatment over time. This software provides maps and the values used to generate the maps. The information provided is intended to be qualitative in nature and when used by a qualified physician may aid in the identification of myocardial enhancement defects and the follow up of such findings.

15. SUBSTANTIAL EQUIVALENCE:

MyoPerfusion, CSMP-001A, performs in a manner similar to and is intended for the same use as the predicate devices in that all are post processing software used to visualize cardiovascular anatomy and pathology. All of these devices utilize CT angiography images/data in order to display various diagnostically useful functions such as the display of polar maps based upon the CT values of the myocardium. In addition, MyoPerfusion provides numerical values used to calculate comparison ratios including Perfusion Index and Transmural Perfusion Ratio. The implementation of these additional features does not result in additional indications of use but rather a variation in the method of displaying the polar maps.

16. SAFETY:

This device is designed and manufactured under the Quality System Regulations as outlined in 21 CFR § 820. All requirements of the Federal Diagnostic Equipment Standard, as outlined in 21 CFR §1020, that apply to this device, will be met and reported via product report.

17. TESTING

Hazard analysis, verification/validation and performance testing conducted through bench testing are included in this submission which demonstrates that the design specifications established for the device have been met and that the perfusion map calculation and auto segmentation used by the software will appropriately display visualization tools used by physicians to analyze myocardial perfusion.

Software Documentation for a Moderate Level of Concern, per the FDA guidance document, "Guidance for the Content of Premarket Submissions for Software Contained in Medical Devices Document" issued on May 11, 2005, is also included as part of this submission.

18. CONCLUSION

MyoPerfusion, CSMP-001A, performs in a manner similar to and is intended for the same use as the predicate devices. Based upon the data presented in this submission including application of design controls and performance data, Toshiba America Medical Systems, believes that **MyoPerfusion, CSMP-001A**, is substantially equivalent in safety and effectiveness to the predicate devices.

DEPARTMENT OF HEALTH & HUMAN SERVICES

Public Health Service

Food and Drug Administration
10903 New Hampshire Avenue
Document Control Center - WO66-G609
Silver Spring, MD 20993-0002

December 12, 2013

Toshiba Medical Systems Corporation
% Mr. Paul Biggins
Director, Regulatory Affairs
Toshiba America Medical Systems, Inc.
2441 Michelle Drive
TUSTIN CA 92780

Re: K132523
Trade/Device Name: MyoPerfusion, CSMP-001A
Regulation Number: 21 CFR 892.1750
Regulation Name: Computed tomography x-ray system
Regulatory Class: II
Product Code: JAK
Dated: September 12, 2013
Received: September 13, 2013

Dear Mr. Biggins:

We have reviewed your Section 510(k) premarket notification of intent to market the device referenced above and have determined the device is substantially equivalent (for the indications for use stated in the enclosure) to legally marketed predicate devices marketed in interstate commerce prior to May 28, 1976, the enactment date of the Medical Device Amendments, or to devices that have been reclassified in accordance with the provisions of the Federal Food, Drug, and Cosmetic Act (Act) that do not require approval of a premarket approval application (PMA). You may, therefore, market the device, subject to the general controls provisions of the Act. The general controls provisions of the Act include requirements for annual registration, listing of devices, good manufacturing practice, labeling, and prohibitions against misbranding and adulteration. Please note: CDRH does not evaluate information related to contract liability warranties. We remind you, however, that device labeling must be truthful and not misleading.

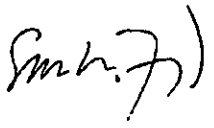
If your device is classified (see above) into either class II (Special Controls) or class III (PMA), it may be subject to additional controls. Existing major regulations affecting your device can be found in the Code of Federal Regulations, Title 21, Parts 800 to 898. In addition, FDA may publish further announcements concerning your device in the Federal Register.

Please be advised that FDA's issuance of a substantial equivalence determination does not mean that FDA has made a determination that your device complies with other requirements of the Act or any Federal statutes and regulations administered by other Federal agencies. You must comply with all the Act's requirements, including, but not limited to: registration and listing (21 CFR Part 807); labeling (21 CFR Part 801); medical device reporting (reporting of medical device-related adverse events) (21 CFR 803); good manufacturing practice requirements as set forth in the quality systems (QS) regulation (21 CFR Part 820); and if applicable, the electronic product radiation control provisions (Sections 531-542 of the Act); 21 CFR 1000-1050.

If you desire specific advice for your device on our labeling regulation (21 CFR Part 801), please contact the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638 2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm. Also, please note the regulation entitled, "Misbranding by reference to premarket notification" (21CFR Part 807.97). For questions regarding the reporting of adverse events under the MDR regulation (21 CFR Part 803), please go to http://www.fda.gov/MedicalDevices/Safety/ReportaProblem/default.htm for the CDRH's Office of Surveillance and Biometrics/Division of Postmarket Surveillance.

You may obtain other general information on your responsibilities under the Act from the Division of Small Manufacturers, International and Consumer Assistance at its toll-free number (800) 638-2041 or (301) 796-7100 or at its Internet address http://www.fda.gov/MedicalDevices/ResourcesforYou/Industry/default.htm.

Sincerely yours,



for

Janine M. Morris
Director, Division of Radiological Health
Office of In Vitro Diagnostics
and Radiological Health
Center for Devices and Radiological Health

Enclosure

Indications for Use

510(k) Number (if known): K132523

Device Name: **MyoPerfusion, CSMP-001A**

Indications for Use:

This software is intended to be used for the visualization of non-reversible perfusion defects (hypo/hyper dense areas) in patients with angina or with a previous myocardial infarct. Included software tools may aid a trained user in monitoring the disease state and treatment over time. This software provides maps and the values used to generate the maps. The information provided is intended to be qualitative in nature and when used by a qualified physician may aid in the identification of myocardial enhancement defects and the follow up of such findings.

Prescription Use __X__ AND/OR Over-The-Counter Use _____
(Part 21 CFR 801 Subpart D) (21 CFR 807 Subpart C)

(PLEASE DO NOT WRITE BELOW THIS LINE-CONTINUE ON ANOTHER PAGE IF NEEDED)

Concurrence of CDRH, Office of In Vitro Diagnostics and Radiological Health (OIR)

(Division Sign Off)
Division of Radiological Health
Office of In Vitro Diagnostic and Radiological Health

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